

REMARKS

Status of Claims

Claims 24, 49-55, 58-63, 70, 71, and 88-92 are pending in the present application, Claims 1-23, 25-48, 64-65, 67-69, 72-74 and 77-87 having been previously canceled, and Claims 56, 57, 66, 75, 76 and 93 having been canceled herein. Claims 24, 50, 51, 52, 54, 60, 61, 88, 89, and 92 have been amended to more clearly define the invention.

Finality of the Present Office Action

Applicant respectfully requests that the finality of the present Office Action be withdrawn and the fee paid for the accompanying Request for Continued Examination be returned.

In the Amendment and Request for Reconsideration filed on June 16, 2006, a declaration from the inventor was made of record. The declaration represented evidence of commercial success of the claimed invention. Such declaration practice is authorized by MPEP 716. In particular, MPEP 716.03(b) specifically addresses evidence of commercial success.

MPEP 2141 explicitly states that such evidence, when offered, MUST be considered. MPEP 707.07(f) requires subsequent Office Actions to answer the substance of applicants' traversal when the same issues are present.

Applicant's evidence of commercial success would be applicable to any obviousness rejection, as it provides evidence that the market has responded favorably to a combination of elements the Examiner considers obvious. Thus, a response to applicant's declaration of June 16, 2006 was required, and not provided. It is unfair to require applicant to Request Continued Examination for the declaration to be considered.

Inventor Declaration Providing Evidence of Commercial Success

The declaration filed June 16, 2006 provides both evidence of commercial success of the invention, and a nexus linking the evidence to the claims.

The evidence of commercial success is not present in terms of sales figures (note that while sales figures do provide one mechanism to provide such evidence, there is no requirement for evidence of commercial success to be limited to or to include such figures). The evidence is the fact that the commercial embodiment of the claimed invention was awarded the 2004 Innovation of the Year Award from the National Society of Laparoendoscopic Surgeons. Significantly, the title of the award indicates that artisans of skill in the laparoscopic arts felt that the commercial embodiment of

the claimed invention was an *innovation*; i.e., a new idea. These artisans of ordinary skill clearly thought the commercial embodiment of the claimed invention was such a great idea it deserved recognition.

Training new laparoendoscopic surgeons is difficult, time consuming, and expensive. The market has responded to the need for training materials by providing many different trainers/simulators. The following patents, already made of record, describe several such trainers developed to meet this need: U.S. Patent No. 5,722,836 and U.S. Patent No. 6,659,776. Prior to the award, commercial embodiments of these inventions were known to the National Society of Laparoendoscopic Surgeons.

If the combination of elements representing the claimed invention would have been obvious to artisans of ordinary skill, then market forces should have responded to the need of laparoendoscopic surgeons for better training tools. The fact that the National Society of Laparoendoscopic Surgeons was so impressed with the commercial value of applicant's claimed invention provides evidence of secondary considerations refuting the obviousness of the combination.

A declaration providing evidence of commercial success must also describe the nexus between the claims and the success. In this case, the declaration notes that the commercial embodiment includes the following elements: a housing, a digital camera attached to a distal end of a boom introduced into the housing. In recognition that the amended claims currently recite additional elements (such as the support structure enabling the camera to be selectively positioned in the housing, the handle, which along with the boom and camera realistically simulates an actual laparoscope, and the relative positions of the simulated laparoscope, the tools and the housing), a revised declaration has been submitted herewith, to ensure that the nexus between the declaration and amended claims exists. Note that each element in the declaration and pending claims does correspond to the commercial embodiment which received the award (FIGURES 2, 3, and 4 of the application as filed correspond to the commercial embodiment which received the award).

The declaration provides evidence of commercial success and a nexus between that evidence and the pending claims. The declaration indicates that the combination of elements defining the claims represents a non-obvious combination.

Obviousness Post KSR

Even post KSR, it is recognized that it is important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the new invention does. This is so because inventions in most, if not all instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.

The KSR court recognized that while a rigid application of a teaching, suggestion, motivation test was not necessary, that some inquiry as to why an artisan of ordinary skill would combine references in a particular manner was appropriate. Applicant respectfully requests that the Examiner enter into the record an articulation of why modifications required to the art to achieve an equivalent invention would have been obvious, rather than impermissible by hindsight, particularly in light of the declaration of commercial success.

Claims Rejected Under 35 U.S.C. § 103

Claims 24, 49-59, 61-63, 66, 71, 75, 76 and 88-93 have been rejected under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent Publication No. 2005/0084833 (Lacey et al. – hereinafter referred to as "Lacey") in view of U.S. Patent No. 5,436,542 (Petelin et al. – hereinafter referred to as "Petelin"). The Examiner asserts that Lacey discloses most of the elements of the rejected claims, but does not disclose brackets that movably and slidingly support the elongate member, in order to enable adjustment of an amount of the elongate member disposed within the practice volume, and to adjust the position of the video camera. However, the Examiner asserts that Petelin discloses a telescopic camera with adjustable brackets, along with a support member. The Examiner acknowledges that Lacey and Petelin do not specifically disclose that the proximal end of the support member is disposed inside the practice volume. The Examiner explains that it would have been obvious to one of ordinary skill to modify Petelin's support member to position the proximal end inside the practice volume of Lacey because such a modification represents a design choice that could be made by the artisan of ordinary skill, as opposed to a novel design. The Examiner has noted that we have not disclosed that this feature solves any particular problem.

Claim 60 has been rejected under 35 U.S.C. § 103 (a) as being unpatentable over Lacey in view of Petelin, and further in view of U.S. Patent No. 5,722,836 (Younker). The Examiner asserts that although the references do not disclose a housing comprising a collapsible frame, that Younker

discloses a videoendoscopic surgical trainer with a collapsible frame. The Examiner concludes that it would have been obvious to one of ordinary skill in the art to incorporate Younker's features into the system and method of Lacey/Petelin in order to design a portable surgical training system.

Claim 70 has been rejected under 35 U.S.C. § 103 (a) as being unpatentable over Lacey in view of Petelin, and further in view of Great Britain Patent No. 2338582 (Day). The Examiner explains that Lacey and Petelin do not expressly teach that the panel is replaceable, but that Day teaches replaceable pre-cut access cavities in a surgical simulator that facilitate the entry of the instruments into the body cavity. The Examiner concludes that it would have been obvious to incorporate this feature of Day into the system of Lacey and Petelin in order to make the maintenance of the device easier.

Applicant respectfully disagrees with this rejection for at least the following reasons.

Claims 56, 57, 66, 75, 76 and 93 have been canceled, thus their rejections are moot.

In the interest of reducing the complexity of the issues for the Examiner to consider in this response, the following discussion focuses on independent Claims 24, 50, 60, 61, and 88. The patentability of each remaining dependent claim is not necessarily separately addressed in detail. However, applicant's decision not to discuss the differences between the cited art and each dependent claim should not be considered as an admission that applicant concurs with the Examiner's conclusion that these dependent claims are not patentable over the disclosure in the cited references. Similarly, applicant's decision not to discuss differences between the prior art and every claim element, or every comment made by the Examiner, should not be considered as an admission that applicant concurs with the Examiner's interpretation and assertions regarding those claims. Indeed, applicant believes that all of the dependent claims patentably distinguish over the references cited. However, a specific traverse of the rejection of each dependent claim is not required, since dependent claims are patentable for at least the same reasons as the independent claims from which the dependent claims ultimately depend.

Patentability of Claim 24 over Lacey in view of Petelin

Claim 24 as amended recites a trainer including a simulated laparoscope and a support structure enabling a digital camera portion of the laparoscope to be moved in a practice volume, where the simulated laparoscope and support structure are disposed relative to the opening such that a student positioned at a front of the housing can use his hands to manipulate the simulated

laparoscope, the support structure, and the plurality of practice surgical tools without having to move away from the front of the housing. Further, the simulated laparoscope comprises:

- (i) a handle having a size and shape simulating a medical laparoscope;
- (ii) an elongate member extending from a distal portion of the handle into the practice volume;
- (iii) a digital video camera coupled to a distal end of the elongate member, such that manually changing a position of the proximal end of the elongate member results in a change in a position of the digital video camera, the elongate member movably supporting the digital video camera externally of the elongate member, the digital camera being thus disposed within the practice volume, the digital video camera being configured to capture a plurality of frames per second, such that the digital video camera can provide a digital video feed of at least a portion of the practice volume; and
- (iv) a data cable having a proximal end and a distal end, the distal end being logically coupled to the digital video camera, the proximal end being configured to logically couple to at least one of a display and a computing device, a first portion of the data cable extending from the digital video camera and the handle being disposed inside the elongate member, a second portion of the data cable extending from the handle to the proximal end of the data cable, the second portion of the data cable extending outwardly and away from a proximal portion of the handle, the data cable being configured to be coupled to a computing device;

Applicant respectfully submits that (1) the suggested combination of Petelin and Lacey does not achieve an equivalent to the trainer defined in Claim 24; and (2) that even if the suggested combination of Petelin and Lacey did achieve an equivalent to the trainer defined in Claim 24, that applicant's evidence of commercial success indicates that the combination is not obvious.

Applicant's evidence of commercial success has been discussed in detail above. In particular, the following two elements appear to significantly contribute to the success of the commercial embodiment: (1) the simulated laparoscope (handle, boom, camera and cable) is so realistic it has fooled experienced users and (2) the trainer is easy to use, in that the user need not move away from the front of the trainer to access the surgical tools, the simulated laparoscope, or the support enabling the camera to be moved.

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With respect to the issue of whether the suggested combination of Petelin and Lacey achieves an equivalent to the trainer defined in Claim 24, applicant respectfully requests the Examiner to consider the following.

Lacey does not disclose that the user should be able to access the surgical tools and the handle from the same location (given Lacey's Figures, it appears awkward for the user to simultaneously access handle 20 and tools 5 from the same position; i.e., it looks like the user would need to lean over quite a bit to reach handle 20). Note also the claimed limitation that the tools and boom pass through the same opening in the trainer, which is not met by Lacey. Petelin does not teach or suggest that the surgical tools and the handle should pass through the same opening and be simultaneously accessible, thus the suggested combination would not exhibit the claimed configuration.

With respect to the simulated laparoscope, the Examiner has previously asserted that Lacey discloses a simulated laparoscope handle, and that Petelin discloses a data cable extending through a hollow boom/shaft. Respectfully, those assertions are not correct. Element 5 in FIGURES 1 and 2 of Lacey does not represent the handle of a laparoscope, rather element 5 is a surgical instrument (i.e., the tool the user is trying to view through the laparoscope). Petelin discloses a REAL laparoscope, not a simulated laparoscope. While the camera/shaft or camera/handle disclosed by Lacey could be considered to be a simulated laparoscope, Lacey's simulated laparoscope is not equivalent, because there is no handle that simulates the handle of an actual laparoscope, and while Lacey discloses the boom to which the camera is attached, Lacey does not teach or suggest the data cable from the camera extending inside the shaft and exiting the handle. The Examiner has argued that Petelin discloses the data cable extending up the shaft. The laparoscope disclosed by Petelin operates fundamentally differently than applicant's simulated laparoscope. In a real laparoscope, the size of the distal tip must be as small as possible. Digital cameras of adequate resolution are generally too large, so a laparoscope uses an external camera (see element 18 in FIGURE 1 of Petelin). The shaft of the laparoscope extending into the patient does not include a data cable attached to a digital camera disposed inside the patient, rather the shaft includes an optical fiber coupled to camera 18, and then camera 18 includes a data cable coupled to a display. It also must be noted that Petelin varies from most laparoscopes because the handle normally manipulated by the user to move the distal end of the laparoscope is replaced by the brackets and gimbals disclosed by Petelin, because a system of servo

motors moves the distal end of the laparoscope, not a user manipulating controls on a handle of the laparoscope. The cited art does not teach the combination of elements defining applicant's simulated laparoscope. That combination of elements has produced a simulated laparoscope that has fooled real laparoscopic surgeons into believing that the trainer included a very expensive laparoscope, and not an inexpensive simulated laparoscope. That has increased the realism provided by the claimed trainer.

Claim 24 thus distinguishes over the cited art, and the rejection of Claim 24 as being obvious over Lacey in view of Petelin should be withdrawn. Dependent claims include each element recited in the independent claims from which they depend, thus each claim depending on Claim 24 is patentable for at least the same reasons. Accordingly, the rejection of Claim 49 as being obvious over Lacey in view of Petelin should be withdrawn.

Patentability of Claim 50 over Lacey in view of Petelin

Claim 50 as amended recites a trainer including a simulated laparoscope and a support structure enabling a digital camera portion of the laparoscope to be moved in a practice volume. The disposition of the simulated laparoscope, the opening in the housing, and the support structure are the same as recited in Claim 24, such that a student positioned at a front of the housing can use his hands to manipulate the simulated laparoscope, the support structure, and the plurality of practice surgical tools without having to move away from the front of the housing. Further, the simulated laparoscope of Claim 50 corresponds to the simulated laparoscope of Claim 24. As discussed above, both of those elements distinguish over the combination of Lacey and Petelin.

Further, even if the suggested combination of Petelin and Lacey did achieve an equivalent to the trainer defined in Claim 50, applicant's evidence of commercial success indicates that the combination is not obvious.

Claim 50 thus distinguishes over the cited art, and the rejection of Claim 50 as being obvious over Lacey in view of Petelin should be withdrawn. Dependent claims include each element recited in the independent claims from which they depend, thus each claim depending on Claim 50 is patentable for at least the same reasons. Accordingly, the rejection of Claims 51-55, 58, and 59 as being obvious over Lacey in view of Petelin should be withdrawn (Claims 56 and 57 having been canceled).

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Patentability of Claim 61 over Lacey in view of Petelin

Claim 61 as amended recites a trainer including a simulated laparoscope and a support structure enabling a digital camera portion of the laparoscope to be moved in a practice volume. The disposition of the simulated laparoscope, the opening in the housing, and the support structure are the same as recited in Claims 24 and 50, such that a student positioned at a front of the housing can use his hands to manipulate the simulated laparoscope, the support structure, and the plurality of practice surgical tools without having to move away from the front of the housing. Further, the simulated laparoscope of Claim 61 corresponds to the simulated laparoscope of Claims 24 and 50. As discussed above, both of those elements distinguish over the combination of Lacey and Petelin.

Further, even if the suggested combination of Petelin and Lacey did achieve an equivalent to the trainer defined in Claim 61, applicant's evidence of commercial success indicates that the combination is not obvious.

Claim 61 thus distinguishes over the cited art, and the rejection of Claim 61 as being obvious over Lacey in view of Petelin should be withdrawn. Dependent claims include each element recited in the independent claims from which they depend, thus each claim depending on Claim 61 is patentable for at least the same reasons. Accordingly, the rejection of Claims 62, 63, 70 and 71 as being obvious over Lacey in view of Petelin should be withdrawn (Claims 66, 75, and 76 having been canceled).

Patentability of Claim 88 over Lacey in view of Petelin

Claim 88 as amended recites a method for using a trainer including a simulated laparoscope and a support structure enabling a digital camera portion of the laparoscope to be moved in a practice volume. The disposition of the simulated laparoscope, the opening in the housing, and the support structure are the same as recited in Claims 24 and 50, such that a student positioned at a front of the housing can use his hands to manipulate the simulated laparoscope, the support structure, and the plurality of practice surgical tools without having to move away from the front of the housing. Further, the simulated laparoscope of Claim 88 corresponds to the simulated laparoscope of Claims 24, 50 and 61. As discussed above, both of those elements distinguish over the combination of Lacey and Petelin.

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Further, even if the suggested combination of Petelin and Lacey did achieve an equivalent to the trainer defined in Claim 88, applicant's evidence of commercial success indicates that the combination is not obvious.

Claim 88 thus distinguishes over the cited art, and the rejection of Claim 88 as being obvious over Lacey in view of Petelin should be withdrawn. Dependent claims include each element recited in the independent claims from which they depend, thus each claim depending on Claim 88 is patentable for at least the same reasons. Accordingly, the rejection of Claims 89-92 as being obvious over Lacey in view of Petelin should be withdrawn.

Patentability of Claim 60 over Lacey in view of Petelin and Younker

Claim 60 as amended recites a trainer including a simulated laparoscope and a support structure enabling a digital camera portion of the laparoscope to be moved in a practice volume. The disposition of the simulated laparoscope, the opening in the housing, and the support structure are the same as recited in Claims 24 and 50, such that a student positioned at a front of the housing can use his hands to manipulate the simulated laparoscope, the support structure, and the plurality of practice surgical tools without having to move away from the front of the housing. Further, the simulated laparoscope of Claim 60 corresponds to the simulated laparoscope of Claims 24 and 50. As discussed above, both of those elements distinguish over the combination of Lacey and Petelin. Younker does disclose a collapsible housing, but not the other additional elements (the simulated laparoscope and the relative position of the components), thus the combination of Lacey, Petelin and Younker does not achieve an equivalent to the structure defined by Claim 60.

Further, even if the suggested combination of Petelin and Lacey did achieve an equivalent to the trainer defined in Claim 60, applicant's evidence of commercial success indicates that the combination is not obvious.

Claim 60 thus distinguishes over the cited art, and the rejection of Claim 60 as being obvious over Lacey in view of Petelin and Younker should be withdrawn.

Patentability of Claim 70 over Lacey in view of Petelin and Day

Claim 70 depends upon Claim 61, and further recites a replaceable panel. Even if it would have truly been obvious to modify Lacey to include the panel disclosed by Day, independent Claim 61 has been extensively modified to recite a simulated laparoscope (whose structural details are not disclosed in the cited art), and a configuration where the relative locations of the opening to

the practice volume, the surgical tools, the simulated laparoscope, and the support structure have been selected to enable a user to manipulate each without moving away from the front of the trainer. As discussed above, both of those elements distinguish over the combination of Lacey and Petelin, and Day does not provide either of the missing elements (thus the combination of Lacey, Petelin and Day does not achieve an equivalent).

Further, even if the suggested combination of Petelin, Day, and Lacey did achieve an equivalent to the trainer defined in Claim 70, applicant's evidence of commercial success indicates that the combination is not obvious.

Claim 70 thus distinguishes over the cited art, and the rejection of Claim 70 as being obvious over Lacey in view of Petelin and Younker should be withdrawn.

In view of the Remarks set forth above, it will be apparent that the claims in this application define a novel and non-obvious invention. The application is in condition for allowance and should be passed to issue without further delay. Should any further questions remain, the Examiner is invited to telephone applicant's attorney at the number listed below.

Respectively submitted

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